

New TREMFYA® (guselkumab) study shows consistent perianal fistula remission across key Crohn's disease patient subgroups

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- New prespecified analyses showed consistent findings across clinically important and difficult to treat subgroups, including patients with prior biologic exposure
- Findings build on first positive results where TREMFYA achieved combined fistula remission rates of up to 28% across dosing groups
- Results come from the first dedicated Phase 3 randomized, placebo-controlled trial in adults managing Crohn's disease with perianal fistula in more than 20 years

SPRING HOUSE, Pa., Oct. 12, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new Phase 3 data showing consistent combined fistula remission outcomes with TREMFYA® (guselkumab) across clinically important subgroups of adults with Crohn's disease with perianal fistula.¹ The prespecified subgroup analyses from the FUZION study are being presented at the American College of Gastroenterology (ACG) 2026 Annual Scientific Meeting and build on previously reported Week 24 results from the overall study population.

In the overall study population, 28% of patients receiving TREMFYA 100 mg q8w and 27% receiving TREMFYA 200 mg q4w achieved the composite endpoint of combined fistula remission^a at Week 24, compared with 10% receiving placebo, making TREMFYA the only IL-23 inhibitor to demonstrate efficacy in a dedicated, randomized, placebo-controlled trial in patients with Crohn's disease with perianal fistula.¹

New subgroup analyses show consistent outcomes across key patient subgroups

Expanding on previously reported results in the overall population, new prespecified subgroup analyses showed greater Week 24 combined fistula remission with TREMFYA versus placebo among:¹

- Patients with greater luminal disease activity at baseline (CDAI ≥ 220): 30% and 21% with TREMFYA 100 mg SC q8w and 200 mg SC q4w, respectively, versus 0% with placebo
- Patients with prior biologic exposure: 21% and 29%, respectively, versus 5% with placebo
- Patients with proctitis at baseline: 26% and 27%, respectively, versus 12% with placebo
- Patients without proctitis at baseline: 29% and 27%, respectively, versus 10% with placebo

Adverse events were consistent with the known safety profile of TREMFYA in Crohn's disease.¹

"Perianal fistula remain one of the most debilitating manifestations of moderate to severe Crohn's disease and many patients continue to experience persistent drainage, pain and complications," said Bruce Sands, MD, MS, Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine, and Chief, Division of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System. "These subgroup analyses show that the outcomes observed with TREMFYA were consistent across clinically important patient populations, further strengthening the evidence supporting its use in this difficult to treat patient population."

Addressing an important need in Crohn's disease

Perianal fistula affects nearly 25% of patients with Crohn's disease and is a severe, often debilitating manifestation associated with pain, persistent drainage, recurrent abscesses and a frequent need for surgical intervention.²

³ FUZION is a dedicated randomized, placebo-controlled Phase 3 study designed to evaluate TREMFYA in adults with Crohn's disease with perianal fistula.

"Johnson & Johnson has a longstanding commitment to advancing the science of inflammatory bowel disease, including for patients living with some of its most complex manifestations," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "FUZION was designed to generate rigorous evidence specifically in Crohn's disease with perianal fistula, helping us deepen our understanding of how TREMFYA can address an area of unmet need."

TREMFYA is the only approved dual-acting monoclonal antibody in inflammatory bowel disease (IBD) that blocks IL-23 while also binding to CD64, a receptor on cells that produce IL-23. IL-23 is a cytokine secreted by activated monocyte/macrophages and dendritic cells that is known to be a driver of immune-mediated diseases including UC. Findings are based on in vitro studies.⁴⁵⁶⁷⁸

Dr. Bruce Sands is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

For a full list of all Johnson & Johnson data being presented at ACG visit:

<https://www.jnj.com/innovativemedicine/immunology/gastroenterology>.

Editor's notes:

- a. Combined fistula remission was defined as complete closure of all external fistula openings with no drainage, without development of new fistulas, and absence of underlying fluid collections on MRI.

About the FUZION study (NCT05347095)

FUZION is a randomized, placebo-controlled, double-blind, multicenter, Phase 3 study designed to evaluate the efficacy and safety of TREMFYA in adults with Crohn's disease with perianal fistula. Patients enrolled in the study had one or more active draining perianal fistulas confirmed by blinded central MRI review, CD Activity Index [CDAI] <350, and inadequate response to oral corticosteroids, azathioprine, 6-mercaptopurine, methotrexate, or up to 2 advanced therapy classes. Patients were randomized 2:2:1 to receive TREMFYA 200 mg intravenous (IV) induction at Weeks 0, 4, 8 weeks followed by TREMFYA 100 mg subcutaneous (SC) induction every 8 weeks (q8w); or TREMFYA 200 mg IV infusion in at Weeks 0, 4, 8 weeks followed by TREMFYA 200 mg SC every 4 weeks (q4w); or placebo.⁹

About Crohn's disease

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans and an estimated four million people across Europe.^{10,11} Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other environmental factors.¹² Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Some patients may also develop fistulas, abnormal connections between the intestine and other organs or tissues, which can be associated with pain, drainage, infection, and substantial impairment in quality of life. Currently no cure is available for Crohn's disease.¹³

About TREMFYA (guselkumab)

Developed by Johnson & Johnson, TREMFYA is the first fully-human, dual-acting monoclonal antibody designed to neutralize inflammation at the cellular source by blocking IL-23 and binding to CD64 (a receptor on cells that produce IL-23). Findings for the dual-acting mechanism are limited to in vitro studies that demonstrate TREMFYA binds to CD64, which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model. The clinical significance of this finding is not known.

TREMFYA is a prescription medicine approved in the U.S. to treat:

- adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.
- adults with moderately to severely active Crohn's disease.

TREMFYA is approved in Europe, Canada, Japan, and a number of other countries for the treatment of adults with moderate-to-severe plaque psoriasis, adults with active psoriatic arthritis, adults with moderate-to-severe Crohn's disease and adults with moderate-to-severe ulcerative colitis.

The manufacturer for TREMFYA is Janssen Biotech, Inc.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA. For more information, visit: www.tremfya.com.

TREMFYA IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA?

TREMFYA is a prescription medicine that may cause serious side effects, including:

- Serious Allergic Reactions. Stop using TREMFYA and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:

o fainting, dizziness, feeling lightheaded (low blood pressure)
o swelling of your face, eyelids, lips, mouth, tongue or throat

o trouble breathing or throat tightness
o chest tightness
o skin rash, hives
o itching

- Infections. TREMFYA may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA and may treat you for TB before you begin treatment with TREMFYA if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

- o fever, sweats, or chills
- o muscle aches
- o weight loss
- o cough
- o warm, red, or painful skin or sores on your body different from your psoriasis

- o diarrhea or stomach pain
- o shortness of breath
- o blood in your phlegm (mucus)
- o burning when you urinate or urinating more often than normal

- Liver problems. With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA. Your healthcare provider may stop treatment with TREMFYA if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:

- o unexplained rash
- o vomiting
- o tiredness (fatigue)
- o yellowing of the skin or the whites of your eyes

- o nausea
- o stomach pain (abdominal)
- o loss of appetite
- o dark urine

Do not use TREMFYA if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA.

Before using TREMFYA, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about TREMFYA?"
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA.
- are pregnant or plan to become pregnant. It is not known if TREMFYA can harm your unborn baby.

Pregnancy Registry: If you become pregnant during treatment with TREMFYA, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA. You can enroll by visiting www.mothersbaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu. The purpose of this registry is to collect information about the safety of TREMFYA during pregnancy.

- are breastfeeding or plan to breastfeed. It is not known if TREMFYA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of TREMFYA?

TREMFYA may cause serious side effects. See "What is the most important information I should know about TREMFYA?"

The most common side effects of TREMFYA include: respiratory tract infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, stomach pain, and bronchitis.

These are not all the possible side effects of TREMFYA. Call your doctor for medical advice about side effects.

Use TREMFYA exactly as your healthcare provider tells you to use it.

Please read the full **Prescribing Information**, including **Medication Guide**, for TREMFYA and discuss any questions that you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Dosage Forms and Strengths: TREMFYA is available as 100 mg/mL and 200 mg/2mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to TREMFYA. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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